SUMMARY OF SAFETY AND EFFECTIVENESS

FOR THE JAN 1 5 2003

MODEL 26-2500, AURA 20, BIPOLAR ELECTROSURGICAL COAGULATOR

K 023482

The *Model 26-2500, Aura 20, Bipolar Electrosurgical Coagulator,* is a general purpose solid state bipolar generator used to supply the RF signal to electrosurgical handpieces used on soft body tissues where a wide range of tissue types, patient conditions, and load impedances are encountered. This indication for use is identical to its predicate device i.e., the *28-1000, Kirwan 50 Watt Bipolar Generator.*

Technological safety and effectiveness is established by the fact that the *Aura 20,* like its predicates, offers well-proven, basic electrosurgical unit technology. Its footswitch activation and solid state circuitry delivers low voltage RF/bipolar energy, interfacing with electrosurgical accessories via its standard female banana jacks. The *Aura 20* differs technologically from its predicates with only minor operational features designed to enhance user interface. The following are some of those features.

- While operating on both 115 and 230 VAC mains supply as its predicates, the *Aura 20* does not require the placement of an external jumper in order to select between the two different voltage levels.
- Activation of the *Aura 20* is via footswitch only, eliminating the optional hand switch activation of its predicates, which is viewed as a little-used option and expendable in order to simplify construction, and limit size.
- While similarly relying on solid-state electronics, the *Aura 20* has been greatly simplified over its predicates by the use of microprocessor technology and modular medical-grade power supply.
- The *Aura 20* uses membrane keypads instead of potentiometers (knobs) as adjustable controls for tonal volume and power level settings.

Performance safety has been tested in accordance with, and found to comply with, the requirements of the applicable sections of the following standards;

- ANSI/AAMI/IEC 60601-1-2 (2001), Medical Electrical Equipment Part 1; General Requirements for the Safety.
- IEC 60601-2-2 (1998), Medical Electrical Equipment Part 2; particular Requirements for the safety of High Frequency Surgical Equipment.
- ANSI/AAMI HF 18 (2001), American National Standard for Electrosurgical Devices

Therefore, the *Aura 20* is substantially equivalent in intended use, technological safety and effectiveness, and performance to both the;

- *26-1500, Kirwan 20 Watt Bipolar Micro Coagulator, and*
- *28-1000, Kirwan 50 Watt Bipolar Generator.*

Kirwan Surgical Products, Inc.
180 Enterprise Drive
Marshfield, MA 02050

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 5 2003

Kirwan Surgical Products, Inc.
Kevin P. Prario
Regulatory Affairs Manager
180 Enterprise Drive
P.O. Box 427
Marshfield, Massachusetts 02050

Re: K023482
Trade/Device Name: Aura 20 Bipolar Electrosurgical Coagulator, Model 26-2500
Regulation Number: 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: October 16, 2002
Received: October 17, 2002

Dear Mr. Prario:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

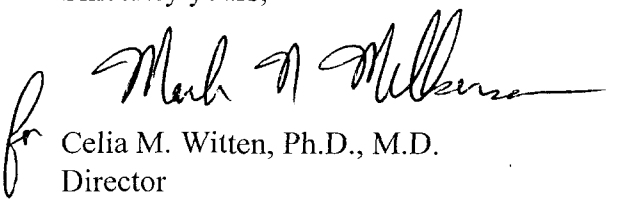
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K023482 Date: 10/16/02

Device Name: Model 26-2500, Aura 20, Bipolar Electrosurgical Coagulator

Indications For use:

The *Model 26-2500, Aura 20, Bipolar Electrosurgical Coagulator* is a general purpose solid state bipolar generator used to supply the RF signal to electrosurgical handpieces used on soft body tissues where a wide range of tissue types, patient conditions, and load impedances are encountered.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Evaluation (ODE)

for Mark N Milhoan

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K023482

(Optional Format 3-10-98)

Prescription Use ✓

PLR 21CFR 801.109